IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Bauman et al.	)
		) Group Art Unit: 2643
Serial No.	10/773,731	)
		) Confirmation No. 8615
Filed:	February 5, 2004	)
		)
For:	HEARING AID SYSTEM	)

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION UNDER 37 CFR 1.132

Sir:

Robert G. Glaser, Ph.D. declares and says that:

1. I am President and owner of Audiology Associates of Dayton, Inc. I have been a practicing Audiologist for over 30 years.

2. I received my B.S. in Speech Pathology and Audiology in 1969 from Bowling Green State University, my M.A. in Audiology in 1971 from Kent State University, and my Ph.D. in Audiology in 1974 from Kent State University.

3. I served as President Elect of the American Academy of Audiology from 1998 to 1999, as President of the American Academy of Audiology from 1999 to 2000 and as Past President of the American Academy of Audiology from 2000 to 2001. I also served on the Board of Directors for the American Academy of Audiology from 1995 to 2000. The American Academy of Audiology is the leading professional organization for

Audiologists throughout the United States with a significant and growing international membership.

4. I served on the Board of Directors for Grandview and Southview Hospitals from 1994 to 2000 and as both Executive Director of Research Centers and Chairman of the Institutional Review Board for the same. I served as Director of Neurodiagnostics and Hearing and Balance Centers in Grandview Hospital from 1992 to 2000. I also served as Chairman of the Ohio Board of Speech-Language Pathology and Audiology from 1985-1992, the licensing and regulatory board for Audiologists and Speech-Language Pathologists practicing in the State of Ohio.

5. I have been a Clinical Professor of Audiology at Ohio University School of Osteopathic Medicine since 1985, an Adjunct Professor of Audiology at Miami University since 1983, and Assistant Clinical Professor of Otolaryngology at Wright State School of Medicine since 1977. I was also Assistant Professor of Audiology at Northern Illinois University from 1974-1976.

6. I have published over 40 articles and provided over 90 podium and course presentations on hearing loss, hearing instruments and fitting, vestibular disorders and assessment, practice management, professional education, reimbursement and policy delineation for both state government and national, professional activities. I have authored a book chapter on private practice and hearing instrument dispensing, and am currently co-authoring a textbook on strategic practice management, which is a comprehensive, pragmatic textbook for graduate students in Audiology, professors, new audiologists and seasoned veterans considering re-engineering of their current practice situations.

7. I am fully familiar with Vivatone's open ear hearing aid system and consider it to be a new category in the field of hearing aid systems. I distinguish this category (as a new category) of hearing aid, which includes a behind-the-ear amplifier and a receiver

suspended within the ear canal, from the other categories of hearing aids that have been developed, marketed and sold for more than 30 years. Other categories include completely in canal (CIC) hearing aids, in-the-canal (ITC) hearing aids, in-the-ear (ITE) hearing aids and behind-the-ear (BTE) hearing aids. The first three types (CIC, ITC and ITE) occlude the ear canal by providing electronics either within the ear canal or immediately external to the lumen of the external auditory canal, in the concha portion of the ear. BTE hearing aids do not occlude the ear canal, but instead provide all components in a housing secured behind the ear. The speaker system is internal to the hearing instrument and is connected to the ear canal via an open tube or earmold with or without various degrees of venting in an attempt to reduce the occlusion effect.

The Vivatone open ear hearing aid is different from the other categories described immediately above in that the speaker assembly is externalized from the instrument and is designed to be inserted into the ear canal to optimize the primary benefit of reducing the occlusion effect and likely enabling greater clarity of signal reproduction by virtue of the proximity of the speaker to the tympanic membrane. Additionally, the Vivatone system is not subject to the effects of tube resonance which is not only measurable in the acoustics laboratory but is noted clinically by patient's responses indicating greater clarity in their existing BTE instruments when aged tubing is changed. Since its inception and development the Vivatone hearing system, its small BTE component with internal microphone assembly, thin speaker wire and the small speaker suspended in the ear canal has been and continues to be considered a revolutionary product design by audiologists charged with fitting and following their patients through the course of aural rehabilitation.

9. Since the introduction of the Vivatone hearing aid, other manufacturers have seen fit to produce hearing aids in this category. Siemens, Interton, Oticon, Hansaton and Phonak (see the attached Phonak literature at Exhibit 1) are a few examples of hearing aid manufacturers that have taken the principal element of the Vivatone hearing and design as described immediately above. These manufacturers may have produced products with additional electronics, software compression, etc., however, the basis of

their offerings in this new class of hearing aids obviously stems from the Vivatone product.

10. I have reviewed Dr. Bauman's patent application and note that Dr. Bauman uses the term "insertion loss" rather than "insertion gain." I note in the background section of Dr. Bauman's application, paragraph 2, which states "Insertion of hearing aid receivers in the ear produces an insertion loss, which reflects a distortion or elimination of the patient's natural or original concha and ear canal resonant characteristics." I also note paragraph 37, which states that "the data analyzed are the values of Probe Real Ear Insertion Response Curve, which consisted of differences between the Probe Real Ear Unaided Response Curve and the Probe Real Ear Aided response curve and the corresponding values repeated while the subject vocalized the letter 'EE'." As an Audiologist, it is clear to me that the "Insertion Effect" test data and the "Insertion Loss" terminology referred to in the specification and the claims refers to the same measurement to determine the effects of electronics or earmold configurations that would reduce the aperture of the lumen of the ear canal. Accordingly, anything that would reduce the cross sectional dimension of the lumen of the ear canal would cause greater insertion loss. The maximum insertion loss would be exemplified by a completely occluded lumen. Read in the light of the specification, the scope of the term "insertion loss" is clear, and the test data is directed to the meaning of "insertion loss" utilized by the claims.

11. It is my understanding that the Patent Examiner refers to FIGURE 11 of Pluvinage and it's description of "insertion gain" on Column 8, lines 15-26. I have reviewed Dr. Bauman's patent application and noted that Dr. Bauman teaches "insertion loss" rather than "insertion gain." As an Audiologist, it is clear to me that the "Insertion Effect" test data and the "Insertion Loss" terminology referred to in the specification and the claims refers to a measurement of a profile in the ear canal with all electronics in the hearing aid turned off. As indicated above, anything that would reduce the cross sectional dimension of the lumen of the ear canal would cause greater insertion loss.

Also indicated above, the maximum insertion loss would be exemplified by a completely occluded lumen. Thus, "insertion loss" (as is claimed by Bauman) is not a function of sound pressure levels (SPL). Pluvinage teaches that its configuration (I have already noted how Pluvinage is different by virtue of use of both a speaker and a sound sampling tube side by side in the ear canal) generates less insertion gain at higher SPL (see the charted line for 80 dB relative to the others). This chart does not teach less than about 3dB of "insertion loss" and does not suggest that in a switched off mode, the side-by-side profile would generate less than about 3dB of "insertion loss." Also, even at 80 dB SPL, for certain frequency ranges, Pluvinage's "insertion gain" is shown to be greater than 3dB in FIGURE 11.

12. I understand that the Examiner believes that the Knowles EH or FK series speakers describe certain "maximum lateral dimension" particulars of Dr. Bauman's claims in light of Pluvinage. Pluvinage describes use of the speaker 44 in a receiver 44 in the ear canal. While the Knowles speaker itself may have a metallic casing, it would always practically include a plastic, or the like, housing material provided around the metallic speaker. While it may be possible to discern the Knowles speaker size, there is no clear indication of how much additional volume the Pluvinage receiver housing would consume. Additionally, inclusion of the microphone sampling tube alongside the receiver would increase the "maximum lateral dimension" which could approach 50 percent of the average, maximum lateral dimensions of ear canals.

13. Reference is further made to the Patent Examiner's rejection of the claims with regard to Pluvinage. The Examiner appears to indicate that the Pluvinage patent teaches that an audiologist possessing ordinary skill in the common art would be motivated and able to modify the hearing aid described by Pluvinage to achieve the Vivatone hearing aid system wherein the only component in the ear canal is the speaker assembly. Pluvinage requires both delivery and sampling of sound within the ear canal. A speaker is placed within the ear canal alongside a tube, which delivers the sampled sound to a monitoring microphone in the external housing of the BTE component. The delivery-

sampling component packaged described by Pluvinage is significantly different from the Vivatone system by virtue of the fact that in Pluvinage, multiple product components are side by side in the ear canal increasing the size of the device section suspended in the ear canal, thus likely adding to the occlusion effect. Additionally, there is the potentially negative effect of tubal resonances, described above. It must also be understood that the proposed modification is not, as described by the Patent Examiner, an obvious modification. With regard to the Patent Examiner's contention that an Audiologist would indeed be motivated to change the design of Pluvinage to avoid infringing patent claims, I can positively state that I would not have known to do this. Audiologists, in general, are neither engineers nor legal or patent experts and would not have considered such an in-office modification as described above to benefit the patients under their care.

14. I also understand that the Patent Examiner has indicated that an audiologist would be motivated to change the CIC device described by U.S. Patent Application Number 20040010181 to Feeley (which is a CIC device that requires use of a mold or a "vented mold" in all cases). Specifically, I understand that the Patent Examiner believes that an audiologist would want to remove the mold and put an eartip (described in U.S. Patent Application Number 2003002700 to Fretz at number 14 in the drawings) around the speaker itself. Fretz simply uses a tube to deliver sound to the ear canal. This is completely different from the Vivatone system and from the Feeley system.

The Vivatone system is <u>not</u> an obvious modification of the Feeley system nor the system described by Fretz. The Feely system is designed to institute the opposite effect of occluding the ear canal, despite Feeley's suggestion that insertion may, by virtue of the depth of penetration of his earmold design, guarantee eradication of the occlusion effect. Audiologists prefer and apply ear molds with and without a variety of venting strategies for a many reasons predicated on the nature and extent of their patient's hearing loss. Fretz, on the other hand, is different simply because it is solely a tube design.

15. The Examiner further indicated that with regard to Dr. Bauman's claim 58, the GN ReSound Air product has a sport lock feature that is a wire. Neither the ReSoundAir

pamphlet nor the GN ReSound article show a wire sport lock. Based on the cited article and brochure, and based on my personal experience fitting the ReSound Air hearing aid, the sport lock is a flexible plastic.

16. I also understand that the Examiner questions the value of the commercial success and copying indicators from various of Mr. Hirsch's Declarations. It is my opinion that Vivatone created a new category of hearing aid when they launched their Vivatone system. It is also my understanding that they may have lost market share when Oticon, Siemens and others introduced their competing products. The Vivatone product was, in my opinion, a clever design that unequivocally turned heads in the audiology community. The Vivatone system was viewed as a logical and realistic approach to reducing the bane of most hearing aid fittings, the occlusion effect. As such, I am not surprised that despite very little advertising, Vivatone's product sales soared before similar competing products were introduced. These sales occurred despite the fact that most Audiologists have fairly strong ties to certain manufacturer's product lines and despite the fact that Vivatone did very little direct advertising (the industry buzz about Vivatone was predominately by word of mouth). Penetration into the marketplace is also a good indicator of success. It is my opinion that Vivatone has done quite well in the marketplace because of their unique configuration and product presentation (the small BTE component with the microphone port, the thin speaker wire, and the small speaker suspended in the ear canal). For many of these same reasons and others, it is clear to me that other major manufacturers of hearing instruments have seen fit to copy the product.

The Patent Examiner has indicated "hearing aids are not the type of device you see advertised on TV or in popular magazines." Thus implying there is little over-the-counter market available to hearing aid manufacturers, he also indicated that hearing aids are distributed in a controlled manner (much like selling blood pressure or cholesterol lowering medication). Licensing boards for audiologists and commercial hearing aid dealers throughout the country effectively control the manner under which hearing aids are dispensed to the public. That does not, however, reduce the manufacturer's need and activity in marketing their products to audiologists and hearing aid dispensers. The

hearing aid industry is heavily affected by advertising. Marketing to the professional audiologist as well as the consumers is an extremely expensive proposition within the hearing aid industry. As such, Vivatone's commercial success should be seen as even more remarkable because of the fact that Vivatone's advertising expenditures were so minimal.

With regard to the Patent Examiner's comments on market data, the Examiner makes certain comparisons of Vivatone's sales relative to certain categories (0.65% of all hearing aid sales; 1.78% of all BTE units). He also references an article by Kirkwood in the Hearing Journal in which GN ReSound CEO Alan Dozier states "...with all the performance improvements, the question is, why do we continue to get 2%, 3% and 4% growth?" The Vivatone configuration gave rise to a new category of hearing aids that is not comparable with hearing aid sales generally, or with BTE sales specifically. The Patent Examiner also indicates that the Vivatone system's success may be attributed merely to "exploratory success", or curiosity of the consumer, rather than to a "got to have it type of success." This is wholly untrue. The benefits of this configuration are readily understood by audiologists, who, as distributors to consumers, purchase these instruments from the manufacturers. As I noted before, audiologists view the Vivatone configuration as a giant leap forward in the industry. While it may be said generally that some improvements in the hearing aid industry may be "incremental", the Vivatone configuration must be considered "segmental" in that it established an entirely new and interesting offering in the dispenser's clinical armamentarium heretofore not available. Simply put, the Vivatone configuration was a head turner from the start.

The Examiner quoted a comment of Alan Dozier from GN Resound: "Not a lot of consumer advertising is being done to build confidence in hearing instruments and build brand awareness." I agree with this comment with regard to conventional hearing aids. However, I completely disagree that this comment relates to this new category of hearing aids. The Vivatone product has spurred a change in the hearing aid industry as it relates to marketing efforts. Indeed, a great deal of advertising is now being done for this category (a "this is not your father's hearing aid" type of response to the Vivatone

configuration). Exemplary of this are the marketing materials of Oticon, Siemens, Hansaton, Interton and Phonak.

The Patent Examiner also refers to the Kirkwood article, page 14, and equates BTE sales with "open fittings" ("mini-BTEs...most of them using open fittings"). Most of the mini-BTEs were designed to fit hearing losses at moderate-to-severe levels and cannot be used effectively in open canal fittings in that there is a distinct need to reduce the inherent feedback that comes with an open fitting (i.e., traditional tube needs to be occluded in certain circumstances to reduce feedback). This raises another distinction between open tube fittings and the Vivatone system, which places a small, non-occluding speaker in much closer proximity to the tympanic membrane than the BTE using a tube. The Vivatone speaker, because of its proximity to the tympanic membrane, uses much less power. Thus, feedback is much less of a concern, and the ear canal does not need to be occluded. Comparison of the open canal Vivatone system (and the similar Oticon, Hansaton, Siemens, etc. systems) with conventional BTE tube systems is, accordingly, really not effective (it is the "apples to oranges" comparison).

The above also relates to the Patent Examiner's assertion that GN ReSound "pioneered" the open fitting. Again, the comparison of BTE tube systems (like the ReSound Air hearing instrument) and the Vivatone open canal receiver system is really not proper. Whether or not ReSound pioneered open tube based systems is really not relevant to the category of hearing instruments containing the Vivatone hearing instrument. Also, as described above, the Pluvinage instrument also does not compare. The Vivatone system is an advancement in that it rejects BTE-tube designs as well as the hybridized tube design of Pluvinage.

I declare under penalty of perjury that the foregoing is true and correct.

_____ January 18, 2007

Robert G. Glaser, Ph.D

configuration). Exemplary f this are the marketing materials of Oticon, Siemens, Hansaton, Interton and Phoı ık.

The Patent Examine also refers to the Kirkwood article, page 14, and equates BTE sales with "open fittin s" ("mini-BTEs...most of them using open fittings"). Most of the mini-BTEs were desi ned to fit hearing losses at moderate-to-severe levels and cannot be used effectively i open canal fittings in that there is a distinct need to reduce the inherent feedback that c mes with an open fitting (i.e., traditional tube needs to be occluded in certain circums unces to reduce feedback). This raises another distinction between open tube fittings a id the Vivatone system, which places a small, non-occluding speaker in much closer prox mity to the tympanic membrane than the BTE using a tube. The Vivatone speaker, beca se of its proximity to the tympanic membrane, uses much less power. Thus, feedback s much less of a concern, and the ear canal does not need to be occluded. Comparison o the open canal Vivatone system (and the similar Oticon, Hansaton, Siemens, etc. sys ems) with conventional BTE tube systems is, accordingly, really not effective (it is the 'apples to oranges" comparison).

The above also relat s to the Patent Examiner's assertion that GN ReSound "pioneered" the open fitting Again, the comparison of BTE tube systems (like the ReSound Air hearing instru ient) and the Vivatone open canal receiver system is really not proper. Whether or not eSound pioneered open tube based systems is really not relevant to the category of h aring instruments containing the Vivatone hearing instrument. Also, as descrit d above, the Pluvinage instrument also does not compare. The Vivatone system is an a lvancement in that it rejects BTE-tube designs as well as the hybridized tube design of Pl vinage.

I declare under penalty of pe jury that the foregoing is true and correct.

January 18, 2007

Robert G. Glaser, Ph.D

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Bauman et al.	) Group Art Unit: 2643
Serial No.	10/773,731	) Confirmation No. 8615
Filed:	February 5, 2004	)
For:	HEARING AID SYSTEM	)

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION UNDER 37 CFR 1.132

Sir:

Dr. Natan Bauman declares and says that:

1. I am an inventor of the above-referenced application. I have been intimately involved in the development and manufacture of the open ear hearing aid system, which includes a behind the ear unit coupled to an open ear speaker within the ear canal.

2. The above-referenced application describes and claims an open ear hearing aid system, including a behind-the-ear amplifier and a receiver suspended within the ear canal, which receiver has an architecture that provides what I generally refer to as an "open ear configuration". More specifically, the application describes and claims, in part:

> a hearing aid system, comprising:
>
> a microphone sampling position located externally of an ear canal of a user,
>
> a receiver comprising a speaker positioned in an open ear configuration and suspended within said ear canal, wherein sound from the microphone sampling position is amplified in accordance with hearing loss programming and passed via electrical connection around a portion of the external ear and through the ear canal opening to the speaker that is positioned within the ear canal in an

open ear configuration, wherein said microphone sampling position and an amplifier are positioned within a behind the ear unit.

Additionally independent claim 1 further requires that the receiver generate about three decibels or below of insertion loss over a portion of human ear audible frequencies.

3. What is referred to as "insertion loss" in the specification and claims, and what was referred to as "insertion effect" in the cited test data, is not "insertion gain." That is, the entire specification, including the test data, describes and claims "insertion loss", wherein the insertion loss is measured with the hearing instrument in place within the canal, but turned off. It is a comparison of the Real Ear Unoccluded Response Curve (completely unaided) with the Real Ear Occluded Response Curve (hearing aid in place, but switched off).

I declare under penalty of perjury that the foregoing is true and correct.

March 13, 2007

Natan Bauman

open ear configuration, wherein said microphone sampling position and an amplifier are positioned within a behind the ear unit.

Additionally independent claim 1 further requires that the receiver generate about three decibels or below of insertion loss over a portion of human ear audible frequencies.

3. What is referred to as "insertion loss" in the specification and claims, and what was referred to as "insertion effect" in the cited test data, is not "insertion gain." That is, the entire specification, including the test data, describes and claims "insertion loss", wherein the insertion loss is measured with the hearing instrument in place within the canal, but turned off. It is a comparison of the Real Ear Unoccluded Response Curve (completely unaided) with the Real Ear Occluded Response Curve (hearing aid in place, but switched off).

I declare under penalty of perjury that the foregoing is true and correct.

Nathan Bauman

March 13, 2007